



PTO/SB/21 (04-04)

IFW

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM (to be used for all correspondence after initial filing)		Application Number	10/792,191			
		Filing Date	March 3, 2004			
		First Named Inventor	Chun-Ying Huang			
		Art Unit	1618			
		Examiner Name	Dameron Levest Jones			
Total Number of Pages in This Submission		Attorney Docket Number	0624-040488			
ENCLOSURES (Check all that apply)						
<table border="0"><tr><td><input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Reply/Amendment <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Documents <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53</td><td><input type="checkbox"/> Drawings <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition for Extension of Time <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____</td><td><input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please identify below) Election with Traverse; Return Receipt Postcard</td></tr></table>				<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Reply/Amendment <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Documents <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawings <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition for Extension of Time <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please identify below) Election with Traverse; Return Receipt Postcard
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Reply/Amendment <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Documents <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawings <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition for Extension of Time <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please identify below) Election with Traverse; Return Receipt Postcard				
Remarks						
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT						
Firm or Individual name	Patricia A. Olosky Registration No. 53,411					
Signature						
Date	February 12, 2007					

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.			
Typed or printed name	Judy Eberle		
Signature		Date	February 12, 2007

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing this form, call 1-800-PTO-9199 and select option 2.

Application No. 10/792,191
Paper Dated February 12, 2007
In Reply to USPTO Correspondence of January 11, 2007
Attorney Docket No. 0624-040488



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/792,191
Applicant : Chun-Ying Huang et al
Filed : March 3, 2004
Title : RADIOACTIVE ARSENIC-CONTAINING COMPOUNDS
AND THEIR USES IN THE TREATMENT OF TUMORS
Art Unit : 1618
Examiner : Dameron Levest Jones
Confirmation No. : 4926
Customer No. : 28289

MAIL STOP AMENDMENT
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

ELECTION WITH TRAVERSE

Sir:

The present communication is submitted in response to the Office Action in the form of a Restriction Requirement dated January 11, 2007 in connection with the above-referenced application. In view of the following remarks, reconsideration of the Restriction Requirement is respectfully requested.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Mail Stop: Amendment; Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date below.

Judy Eberle
(Name of Person Mailing Paper)

Judy Eberle
Signature

02/12/07
Date

In the Office Action, claims 1-17 have been restricted under 35 U.S.C. §121 between the following allegedly distinct Groups:

Group I, including claims 1-5 and 10-17 that are drawn to a pharmaceutical composition comprising a radioactive arsenic-containing compound selected from the group consisting of As_2O_3 , As_2S_3 , As_2S_2 and combinations thereof; and

Group II, including claims 6-9 that are drawn to a process of preparing a pharmaceutical composition of Group I.

Further, the Examiner has required election of a single species for prosecution under 35 U.S.C. §121 between the following allegedly distinct Species:

Species I. As_2O_3 ;
Species II. As_2S_3 ; and
Species III. As_2S_2 .

Finally, the Examiner has required that the tumor or cancer of interest be identified.

The present invention is directed to a pharmaceutical composition comprising a radioactive arsenic-containing compound selected from the group consisting of As_2O_3 , As_2S_3 , As_2S_2 and combinations thereof, as well as a process for preparing the same. Group I is directed to the pharmaceutical composition of the present invention and the claims of this Group are classified in class 424, subclass 1.61. Group II is directed to the process of preparing the pharmaceutical composition and the claims of this Group are classified in class 424, subclass 1.11.

Applicants respectfully traverse the restriction of Groups I and II on the grounds that Applicants believe a search with respect to Group I would be co-extensive with a search directed toward Group II and, therefore, would not pose an undue burden on the Examiner. However, should the Examiner maintain the restriction requirement as to Groups I and II, Applicants provisionally elect Group I for initial examination.

With respect to the election of either As_2O_3 , As_2S_3 , or As_2S_2 as the Species of the invention for initial examination, Applicants respectfully assert the following:

Referring to the statements set forth on page 2, line 23 to page 3, line 6 of the present specification, arsenic trioxide (As_2O_3) achieved a complete remission rate of 90% in

the treatment of relapsed acute promyelocytic leukemia (Shen Z.X. et al., Blood (1997), 89: 3354), and other arsenic-containing substances such as "Composite Indigo Naturalis Tablets" and pure tetraarsenic tetrasulfide (As_4S_4) can achieve complete remission rates of 98% and 84.9%, respectively.

In view of the aforesaid, evidently, As_2O_3 , As_2S_3 and As_2S_2 each are effective in the treatment of promyelocytic leukemia. According to the present invention, the As atom contained therein can be converted to a radioactive arsenic isotope via a neutron irradiation treatment. Given this, these three compounds should not be deemed patentably distinct Species.

In addition, it is described on page 4, lines 4-13 that "In 2002, Miller et al., propounding the possible mechanisms of actions of arsenic trioxide in *Cancer Research* (2002), 62:3893-3903, stated that these actions might result in the induction of apoptosis, the inhibition of growth and angiogenesis, and the promotion of differentiation, and that because arsenic affected so many cellular and physiological pathways, a wide variety of malignancies, including both hematologic cancer and solid tumors derived from several tissue types, might be susceptible to therapy with arsenic trioxide." Apparently, the therapeutic effect of As_2O_3 , in the treatment of cancer is attributed to the As atom contained therein. Since As_2O_3 , As_2S_3 and As_2S_2 each contain an As atom, which can be converted to a radioactive arsenic isotope according to the presently claimed invention, the three compounds should not be deemed patentably distinct Species.

Further, the claims of the present invention are directed to a composition containing at least one of As_2O_3 , As_2S_3 , and As_2S_2 and a process for preparing the same. As such, examination of one of the species would be co-extensive with the examination of the other species identified by the Examiner because the species can exist in the composition concurrently. Accordingly, restriction of the claims between the above-referenced, allegedly distinct species is inappropriate. However, should the Examiner maintain the restriction requirement as to the following Species: As_2O_3 , As_2S_3 , or As_2S_2 , Applicants provisionally elect As_2O_3 encompassed by all of pending claims 1-17, and claims 1-5 and 10-17 of Group I, as the Species for initial examination.

With respect to identifying the tumor or cancer of interest, Applicants respectfully assert the following:

It is described on page 4, lines 4-13 that “In 2002, Miller et al., propounding the possible mechanisms of actions of arsenic trioxide in *Cancer Research* (2002), 62:3893-3903, stated that these actions might result in the induction of apoptosis, the inhibition of growth and angiogenesis, and the promotion of differentiation, and that because arsenic affected so many cellular and physiological pathways, a wide variety of malignancies, including both hematologic cancer and solid tumors derived from several tissue types, might be susceptible to therapy with arsenic trioxide.” These statements clearly reveal the fact that arsenic is effective in the treatment of both hematologic cancer and solid tumors derived from several tissue types, rather than liver cancer only.

In addition, referring to the paragraph bridging pages 4 and 5 of the specification, it is clear that arsenic trioxide can inhibit growth of many cancer cell lines and promote apoptosis in the cancer cell lines. Besides, clinical trials of arsenic trioxide were conducted in connection with hematologic malignancies (including acute promyelocytic leukemia, acute myeloid leukemia (AML), acute lymphocytic leukemia, chronic myelogenous leukemia (CML), non-Hodgkin's lymphoma, Hodgkin's lymphoma, chronic lymphocytic leukemia, myelodysplastic syndrome and multiple myeloma), and solid tumors (including prostate cancer, cervical cancer and bladder cancer)(See *Murgo A.J., The Oncologist* (2001), 6 (suppl 2):22-28).

It is further stated in the paragraph bridging pages 5 and 6 of the specification that “WO 99/24029 (corresponding to CN 1285743A) discloses methods for the treatment of leukemia, lymphoma, and solid tumors, which includes administering to a patient a therapeutically effective amount of arsenic trioxide or an organic arsenical”. In fact, WO 99/24029 also discloses other therapeutic methods and combination therapies, such as chemotherapeutics, radioprotectants, radiotherapeutics, and the like, so as to improve the life quality of cancer patients.

In view of the aforesaid, the use of arsenic compounds in the treatment of cancers is not limited to specific types of cancers/tumors. Therefore, it is believed that the radioactive arsenic-containing compound according to this invention can be used in the treatment of a variety of cancers as enumerated above. However, should the Examiner require the identification of the tumor or cancer of interest, Applicants provisionally identify liver tumors as the subject matter of interest.

For the Examiner's convenience, the following Table identifies the location in the present specification of the statements relied upon in the foregoing arguments:

TABLE

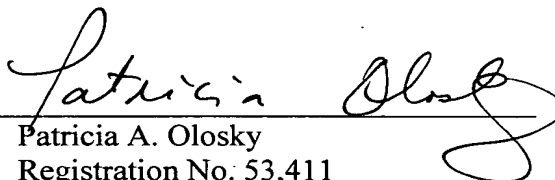
Location in the Specification	Cancer/ tumor	Reference
p.2, L23 – L27	acute promyelocytic leukemia	<i>Shen Z.X. et al., Blood (1997), 89: 3354</i>
p.2, L27 – p.3, L6	acute promyelocytic leukemia	<i>Wang Z.Y., Cancer Chemother Pharmacol (2001), 48 (suppl 1): S72-S76</i>
p.3, L7 – L14	acute promyelocytic leukemia	<i>Shen Y, et al., Leukemia (2001), 15: 735-741</i>
p.3, L7 – L14	acute promyelocytic leukemia	<i>Muto A et al., Leukemia (2001), 15(8): 1176-1184</i>
p.4, L4 – L13	hematologic cancer and solid tumors derived from several tissue types	<i>Cancer Research (2002), 62:3893-3903</i>
p.4, L14 – p.5, L2	hematologic malignancies (acute promyelocytic leukemia, acute myeloid leukemia (AML), acute lymphocytic leukemia, chronic myelogenous leukemia (CML), non-Hodgkin's lymphoma, Hodgkin's lymphoma, chronic lymphocytic leukemia, myelodysplastic syndrome and multiple myeloma) and solid tumors(prostate cancer, cervical cancer and bladder cancer)	<i>Murgo A.J., The Oncologist (2001), 6 (suppl 2):22-28</i>
p.5, L18 – L20	liver tumor (mice)	<i>Lin et al., "Study on Anti-tumor Activity of Arsenic Trioxide," China Journal of Chinese Materia Medica (1999), 24(3): 1-3</i>
p.5, L21 – L25	leukemia, lymphoma, and solid tumors	WO 99/24029 (corresponding to CN 1285743A)

Application No. 10/792,191
Paper Dated February 12, 2007
In Reply to USPTO Correspondence of January 11, 2007
Attorney Docket No. 0624-040488

In view of the above remarks, withdrawal of the restriction requirement is respectfully requested. However, in the event the Examiner maintains the restriction requirement, Applicants hereby provisionally elect, with traverse, to prosecute Group I, Species As₂O₃ that corresponds to claims 1-5 and 10-17 of Group I and liver tumors as the subject matter of interest. Applicants make this election without prejudice to the later filing of a divisional application directed to the non-elected claims.

Respectfully submitted,

THE WEBB LAW FIRM

By 

Patricia A. Olosky
Registration No. 53,411
Attorney for Applicants
700 Koppers Building
436 Seventh Avenue
Pittsburgh, PA 15219-1845
Telephone: 412-471-8815
Facsimile: 412-471-4094
E-mail: webblaw@webblaw.com